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UNITED STATES DISTRICT COURT

for the

Eastern District of Michigan

United States of America)

v.

Gene HARDWICK

Case:2:11-mj-30131

Judge: Unassigned,

Filed: 03-16-2011 At 02:19 PM

USA v. Gene Hardwick (ml)

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of January 8, 2009 - January 20, 2010 in the county of Wayne in the
Eastern District of Michigan, the defendant(s) violated:

Code Section

Title 21 United States Code,
Section(s):

331(c), 331(a), 331(i)(3), 352(a),
352(f), and 333(a)(2)

Offense Description

The defendant has caused misbranded and counterfeit prescription drugs to be shipped into the United States from China and, after receiving such drugs, distributed them for profit to customers without a valid prescription.

This criminal complaint is based on these facts:

See Attached Affidavit

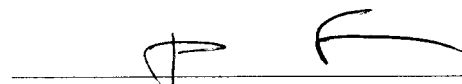
☒ Continued on the attached sheet.


Complainant's signature

Patrick J. Whelan, Special Agent
Printed name and title

Sworn to before me and signed in my presence.

Date: 3/16/11


Judge's signature

City and state: Detroit, Michigan

R. Steven Whalen, U.S. Magistrate Judge
Printed name and title

AFFIDAVIT

I, the undersigned Special Agent swear and depose as follows:

I, Patrick J. Whelan, do hereby state that I am a criminal investigator with the United States Food and Drug Administration, Office of Criminal Investigations (FDA/OCI). I am currently assigned to the Chicago Field Office and have been employed by the FDA since July of 2007. I have approximately seventeen years of law enforcement experience, including six years as a criminal investigator with United States Immigration and Customs Enforcement in Detroit, Michigan, and eight years of experience as a municipal Police Officer and Detective. My duties as a criminal investigator with FDA/OCI include conducting investigations of criminal violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "FDCA").

This affidavit is being presented to establish probable cause for the issuance of an arrest warrant for Gene HARDWICK ("HARDWICK"). Your Affiant is currently investigating HARDWICK's purchase, receipt, and distribution of fake Viagra® and Cialis® pills. As discussed in more detail below, Hardwick purchases the fake Viagra® and Cialis® from China. The drugs arrive in the United States concealed in a handbag that is placed inside of a shipping box. The label on the shipping box identifies the contents as either a "Gift Bag" or "Gift Bag and Accessories." The pills on their face appear to be that of authentic Viagra® and Cialis®. They are the same color, shape, and bear the similar engravings to the authentic products. Subsequent testing of these products, however, has shown that they are not authentic. HARDWICK, moreover, has admitted to agents that after receiving the drugs, he sells them for profit - which he described as "a little hustle."

This affidavit sets forth facts which establish probable cause to believe that HARDWICK violated the FDCA by:

- (1) receiving and causing the receipt of misbranded drugs in interstate commerce, and the delivery or proffered delivery of such drugs for sale or otherwise with the

intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(c), 352(a) and (f), and 333(a)(2);

(2) introducing and causing the introduction or delivery for introduction of misbranded drugs into interstate commerce with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a), 352(a) and (f), and 333(a)(2); and

(3) selling or dispensing, and holding for sale or dispensing, of a counterfeit drug with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(i)(3) and 333(a)(2).

I. FACTS SUPPORTING PROBABLE CAUSE

On January 20, 2010, the section of the Department of Homeland Security known as Customs and Border Protection (“CBP”), which is responsible for monitoring the entry of merchandise into the United States, examined an Express Mail Service (“EMS”) package bearing tracking number EE253023255CN at the O’Hare International Mail Branch in Chicago, Illinois. The shipping label indicates the package was shipped from Shijia Zhuang, China. The label identified the recipient of the package as Gene HARDWICK, 100 Riverfront Drive, Apartment 902, Detroit, Michigan 48226. The shipping label described the contents of the package as a “Gift Bag” and described the value of the contents as sixteen dollars (\$16.00).

Upon opening the package, CBP found a handbag. Inside the handbag CBP found an unlabeled plastic bag that contained approximately nine hundred and one (901) pills of what appeared to be Viagra®. Like authentic Viagra®, the pills were diamond-shaped, blue in color, and were embossed with “Pfizer” on one side and “VGR 100” on the other side.

CBP determined the handbag and the purported Viagra® violated trademark laws and seized the package for violation of 19 U.S.C. §1526 (E), Importation of Counterfeit Goods. CBP

then turned the package over to FDA/OCI. Your affiant, after receiving the package from CBP, sent a sample of the purported Viagra® to the FDA's Forensic Chemistry Center ("FCC") for testing.

Approximately one week later, on January 27, 2010, your affiant and Immigration and Customs Enforcement ("ICE") Special Agent Michael Pearl interviewed Gene HARDWICK at 100 Riverfront Drive, Apartment 902, Detroit, Michigan. We identified HARDWICK with his Michigan picture driver's license as Gene Roland HARDWICK, whose date of birth is January 8, 1962. HARDWICK also provided with a cellular telephone number of (586) 477-7603.

When we met HARDWICK, your affiant advised him that he was not under arrest and was free to leave at any time during the interview. We then asked him about the 901 pills of alleged Viagra® seized at the O'Hare International Mail Branch. HARDWICK stated he thought the pills were generic - a legitimate replica of authentic Viagra® - and not a counterfeit product. He also stated that he has purchased Viagra® and Cialis® from various Internet websites associated with China for the past twelve months. He explained that he will purchase Viagra® and Cialis® for fifty cents (\$.50) per pill. HARDWICK stated that the pills will usually arrive in a purse or women's bag. HARDWICK stated that he will retain a portion of the pills for personal use and admitted he will sell the Viagra® and Cialis® to associates for three dollars (\$3.00) to four dollars (\$4.00) per pill. HARDWICK stated he makes approximately two hundred dollars (\$200.00) per week and described his activity as "a little hustle."

HARDWICK explained he will pay for the pills via Western Union and that he wires the funds to a recipient in China using the name Zhao Jie ZHU. HARDWICK estimated he has wired approximately eight thousand dollars (\$8,000.00) to Zhao Jie ZHU over the past twelve

(12) months. HARDWICK admitted he recently placed another order of pills from China and stated the pills were being shipped via EMS tracking number EE253923202CN.

HARDWICK provided us with his consent to search his residence and vehicle, and he also signed a FDA/OCI consent to search form. During a search of his residence, we found an EMS shipping label bearing EMS tracking number EE253023304CN addressed to 38899 Creekridge Circle, Clinton Township, Michigan 48036. The shipping label described the contents as a "gift bag and accessories." Additionally, we found the following receipts for Western Union Wire transfers:

- October 26, 2009 - \$737.00 wired from Gino HARDWICK to Zhao Jie ZHU
- December 16, 2009 - \$708.00 wired from Gino HARDWICK to Zhao Jie ZHU
- January 25, 2010 - \$914.00 dollars wired from Gino HARDWICK to Zhao Jie ZHU

During the search of HARDWICK's vehicle, we found twenty boxes of purported 20 mg Cialis®. Each box bore a label indicating that the box contained four film-coated tablets pf Cialis®, and that each tablet consist of 20 mg of Tadalafil. The front of the boxes are embossed with the name "Lilly," while the back of the boxes bear addresses for "Eli Lilly and Company" in the United Kingdom and Ireland.

Inside each box we found two blister packages each containing two almond-shaped pills of purported 20 mg Cialis®. We also found a package insert or "leaflet" inside the box of purported Cialis.® The top of the leaflet described the contents of the box as "Cialis® 20 mg film-coated tablets," and also provided the name, "tadalafil." The leaflet also stated that inside the leaflet would be found answers to the following:

1. What CIALIS is and what it is used for
2. Before you take CIALIS
3. How to take CIALIS
4. Possible side effects

5. Storing CIALIS
6. Further information

In the "Further Information" section, the leaflet provides contact information for a local representative of Eli Lilly in several European countries. The bottom of the leaflet states, "This leaflet was last approved on November 2005."

We also found in the vehicle two boxes of purported 200 mg Cialis®. The front of the box bears the names "Cialis," "TADALAFIL," "Tadalafil," and "tadalafil," the statement "NEW," and the purported dosage amount of "200 mg." We found inside each box a bottle containing ten, almond-shaped pills, black in color, embossed with the lettering "C200." We also found inside each box a package insert or "leaflet." The top of the leaflet identified the contents of the box as "Cialis 200 mg," "TADALAFIL," "Tadalafil," and "tadalafil." The leaflet also stated that inside the leaflet would be found answers to the following:

1. What CIALIS is and what it is used for
2. Before you take CIALIS
3. How to take CIALIS
4. Possible side effects
5. Storing CIALIS
6. Further information

The body of the leaflet described the contents as "CIALIS 100 mg film-coated tablets," but also stated "[e]ach tablet of CIALIS contains 200 mg of tadalafil." The leaflet also identifies the "[m]anufacturer" as "Eli Lilly and Company Ltd" in the "United Kingdom." The bottom of the leaflet states, "This leaflet was last approved on August 2004." As discussed above, the FDA has approved has not approved Cialis® in a 200 mg dosage form.

Your affiant subsequently sent samples of the purported 20 mg and 200 mg Cialis® tablets we obtained from HARDWICK's car to the FCC for testing.

On May 10, 2010, your affiant received the results of FCC analysis of the purported Viagra® CBP seized at the O'Hare International Mail Branch, as well as the purported 20 mg and 200 mg Cialis found in HARDWICK's vehicle. FCC determined the purported Viagra was not consistent with authentic Viagra®. In addition, FCC found that the tablets only contained 69 mg of Sildenafil per tablet, or 69 percent of the declared 100 mg per tablet.

FCC also determined that the purported 20 mg Cialis was not consistent with authentic 20 mg Cialis®. FCC found that the pills actually contained Sildenafil, not Tadalafil, which is the active ingredient in authentic Cialis®. Also, FCC found that the tablets contained 42 mg of Sildenafil per tablet, instead of 20 mg of Tadalafil per tablet declared on the labeling.

Finally, the FCC determined that the purported 200 mg Cialis, like the purported 20 mg Cialis, contained Sildenafil rather than Tadalafil. Moreover, FCC found that the purported 200 mg tablets only contained 124 mg of the active ingredient (Sildenafil) per tablet.

Your affiant has queried records maintained by the State of Michigan Department of Community Health to determine if Gene HARDWICK is a licensed health care practitioner. The records did not reveal any state licenses for HARDWICK.

Your affiant also has reviewed records maintained by Western Union, a financial services company specializing in the transfer of funds, regarding transactions involving HARDWICK. My review found that from on or about January 1, 2009, through on or about January 25, 2010, HARDWICK wired approximately thirteen thousand three hundred eighty-three dollars (\$13,382.00) to Zhao Jie ZHU through a series of twenty-five wire transfers. The following is a record of the wire transfers from HARDWICK to Zhao Jie ZHU.

Send	Paid	Recording	Sender	Receiver	Amount Paid	Sender ID
01/08/2009	01/09/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAOJIE ZHU	\$370.00	7347877410
01/18/2009	01/19/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$615.00	7347877410
02/17/2009	02/22/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$375.00	7347877410
03/04/2009	03/05/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAOJIE ZHU	\$775.00	7347877410

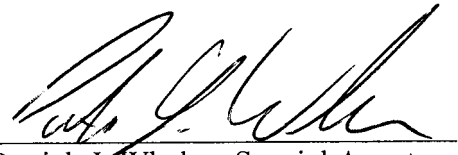
03/26/2009	03/26/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAOJIE ZHU	\$225.00	7347877410
04/07/2009	04/08/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$385.00	7347877410
04/19/2009	04/20/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$897.00	7347877410
05/22/2009	05/23/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$80.00	7347877410
05/31/2009	05/31/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$510.00	7347877410
06/14/2009	06/18/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$580.00	7347877410
06/23/2009	06/24/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$350.00	7347877410
07/03/2009	07/04/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$250.00	7347877410
07/09/2009	07/10/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$495.00	7347877410
07/27/2009	07/27/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$652.00	7347877410
08/20/2009	08/20/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$465.00	7347877410
08/31/2009	09/04/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$337.00	5864777601
09/02/2009	09/04/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$790.00	5864777601
09/17/2009	09/17/2009	CLINTON TOWNSHIP	GENISE HARDWICK	ZHAO JIE ZHU	\$760.00	5864777601
10/04/2009	10/05/2009	CLINTON TOWNSHIP	GENE HARDWICK	ZHAO JIE ZHU	\$530.00	5864777603
10/08/2009	10/08/2009	DETROIT	GENISE HARDWICK	ZHAO JIE ZHU	\$357.00	5864777601
10/26/2009	10/26/2009	CLINTON TOWNSHIP	GINO HARDWICK	ZHAO JIE ZHU	\$723.00	5864777601
12/02/2009	12/03/2009	FERNDAL	GINO HARDWICK	ZHAO JIE ZHU	\$554.00	5864777603
12/16/2009	12/16/2009	DETROIT	GINO HARDWICK	ZHAO JIE ZHU	\$694.00	5864777603
01/09/2010	01/09/2010	DETROIT	GINO HARDWICK	ZHAO JIE ZHU	\$714.00	5864777603
01/25/2010	01/26/2010	DETROIT	GINO HARDWICK	ZHAO JIE ZHU	\$900.00	5864777603
				Total:	\$13,383.00	

I attempted to locate the package of purported Viagra and/or Cialis being sent to HARDWICK via EMS tracking number EE253923202CN. Queries of the United States Postal Service on-line tracking records revealed EMS tracking number EE253923202CN was accepted in China on January 29, 2010, and was delivered to an address in Clinton Township, Michigan, on February 4, 2010. I attempted to intercept the package throughout the delivery process and made numerous unsuccessful attempts to contact Gene HARDWICK.

On February 5, 2010, I spoke with HARDWICK about the shipment. He stated that unknown subjects broke into his vehicle and stole the package. HARDWICK further stated he filed a report with the Detroit Police Department. I have obtained the Detroit Police Department report documenting the theft of merchandise from his vehicle while it was parked in Detroit, Michigan. The stolen merchandise listed in the police report did not include pharmaceutical products.

II. CONCLUSION

Based on the above described information, I have probable to believe Gene HARDWICK has engaged in the following FDCA violations: (1) receiving and causing the receipt of misbranded drugs in interstate commerce, and the delivery or proffered delivery of such drugs for sale or otherwise with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(c), 352(a) and (f), and 333(a)(2); (2) introducing and causing the introduction or delivery for introduction of misbranded drugs into interstate commerce with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a), 352(a) and (f), and 333(a)(2); and (3) selling or dispensing, and holding for sale or dispensing, of a counterfeit drug with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(i)(3) and 333(a)(2).



Patrick J. Whelan, Special Agent
U.S. Food and Drug Administration
Office of Criminal Investigations

Signed and sworn to before me
this 16th day of March, 2011



United States Magistrate Judge